Exhibit E

Deposition of:

David Kessler , M.D.

October 5, 2016

In the Matter of:

Clare-Austin vs. C.R. Bard

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trying to think. Obviously, you know, I have my medical degree, have worked alongside in medical schools with bioengineers, I've created departments of bioengineering, in essence. So -- and FDA, a very big part of FDA, the regulation of medical devices has to do with engineers. So while I may have engineers in the room, it's that interface with engineers and the safety and efficacy that I have expertise in.

Q. I believe my question was do you have any training in engineering?

MR. LOPEZ: I think he answered that, I think he answered it.

MR. NORTH: I don't think he did. He supplied his experience but no training.

THE WITNESS: So certainly in medical school, bioengineering is an aspect of medical school training.

BY MR. NORTH:

Q. Other than taking a course in medical school on biomedical engineering, have you taken any other formal classes in engineering?

A. No, but I've -- you know, again, I've had engineers work for me in assessing the safety and efficacy of devices.

Q. Have you ever designed a medical device?

A. Actually, I have.

Q. Have you ever designed an implantable medical device?

A. I regulated them, I assessed them, I take the designs and determine whether they were either safe and effective or substantially equivalent. So no, usually I'm handed a design by somebody and then the question is what -- how should I take those designs and assess them for safety and efficacy or, you know, substantial equivalence.

Q. So while you have assessed and analyzed designs of medical devices, you have never personally designed an implantable medical device; is that correct?

A. I've regulated, I think is the way to say that, I regulated the design of medical devices.

Q. Have you designed one, though? I understand you regulated one. Have you personally designed an implantable medical device?

A. I don't believe from beginning to end I've done the whole thing. We may have had certain meetings on how things should have been designed at FDA, but no. We take the designs and assess those designs for safety and efficacy and substantial equivalence.

Q. When were you first retained to assist in this litigation?

A. Retained is a, you know, a legal term. I can

Q. Dr. Kessler, we've now marked a copy of the schedules to your report as Exhibit 6; is that correct?

A. Yes.

Q. Now, Schedule 1 involves a listing of all the plaintiffs, at least as of some date, in this litigation; correct?

A. Yes.

Q. You did not prepare that yourself, did you?

A. No. I think there's a footnote that tells you exactly who prepared the schedules, I'm sure you've read it. So if you look at my report, in the page on schedules, it says "All schedules were prepared by staff from legal counsel at my request and subject to my review."

Q. And why did you want a list of all the plaintiffs?

A. Because if you asked me who this report -- who the plaintiffs are -- right? -- in this matter, I need to be able to -- I mean, I thought I would want to be able to answer that question. I mean, and so if you want to know who this report was done in anticipation of as part of the MDL in addition to Austin, I think that was fair information.

Hopefully, everything in -- the goal in the schedules is just to have objective information. If you

disagree with anything, let me know, happy to consider it and fix it. It was just to make sure that you and I -- that I had information available to me.

Q. In the list, the spreadsheet with the names of the plaintiffs, for some of them there's a description of the medical course or complication; correct?

A. Yes.

Q. And you didn't prepare that yourself, did you?

A. No, I didn't. Again, I refer you to the footnote on how it was prepared. My goal was -- I didn't want to make people do more work, but I did ask for a list of all the plaintiffs to which this report would be -- could be applicable so we could know that.

Q. But you didn't revise any of those entries about the medical condition or course, did you?

A. I didn't touch any of those and I make no representation to that. And, again, if there's any disagreement with any of those, I -- you know, let's fix those. It's not essential, I just wanted the plaintiffs' names.

Q. Let's look at Schedule 2, if we can.

A. Yes.

Q. Did you prepare -- did someone else prepare that history and chronology for you?

A. Yes. And, again, please understand that I

specifically -- I prepared my report myself, that's every word myself. These are factual things that others have prepared specifically so if we want to know something, I mean, it's available.

Q. Did you revise this yourself at all?

A. I don't think I -- I don't think so.

Q. Schedule 3 is a diagram of the predicate and prior predicate devices. Did someone else prepare that?

A. Yes, but I actually -- I did -- I mean, I wanted to get it right, so I did have more input on this. For example, there were multiple SNFs, and so when the first version came, it didn't have all the SNFs and I sent it back, for example. Again, this should be, again, objective facts that we should all be able to agree on.

Q. Did you make any changes to the draft of this other than to add the additional SNFs?

A. I wouldn't know how to do a chart like this.

Q. But, substantively, did you ask if there's anything else?

A. I may have -- I also was aware there's multiple G2s, so I wanted to make sure this was as complete and comprehensive. So, if anything, I made sure -- let's just make sure there's nothing left off this, that was my goal, that was my contribution.

Q. But he's with one of the firms?

A. He's with a firm. I don't know who he was with. Again, let me just be clear, these data should be just a way, if we want to have a discussion, of quickly access the data, I tried to get it in one place.

Q. But with these other schedules, who generally prepared these; was it a single law firm or a number of law firms, all these schedules?

A. There were different people prepared them, I assume, I think at different firms.

Q. Okay. Prior to your involvement in this litigation, had you ever reviewed any filter migration testing before?

A. I don't re -- I'd have to go back to see what we did at FDA. I have some recollection of non-vena cava kind of filters, but I have to go back. It may have been in a surgical context, but I have to go back. It's been more than a decade.

Q. You don't recall that specifically, as you sit here?

A. I remember getting involved in other programs, I believe in a non-vena cava context, I'm pretty sure, but I'd have to go back and check the records.

Q. Have you ever conducted any migration resistant testing yourself?

BY MR. NORTH:

Q. Okay. Schedule 10, the list of names, officials named in the report. Who prepared that for you?

A. Actually, I don't know. This is just specifically every time there was a memo or an email or a report that was cited, I just wanted to have a list of everyone's title to see who was cited.

Q. And so you did that yourself?

A. No, I don't know who did this. I did not do this.

Q. Okay.

A. Again, literally, it's just every name in my report is in this list, again administerial.

Q. Schedule 11, deposition citations.

A. Yes.

Q. Do you know who prepared this?

A. Nicholas Graham.

Q. From Mr. Lopez's office?

A. Yes. So what -- you didn't ask me a question.

Q. Number 12, schedule, timeline of FDA and Bard communications. Do you know who prepared this?

A. I don't recall. I have another log that I guess was done by Bard. I don't know who did this one.

Q. Did you audit this one to see that it was

comprehensive or if it omitted anything?

A. So I actually -- there is another Bard list. I have a Bard chronology -- happy to make it available -- that is more comprehensive on the years 2009, 2010, it's an internal log. So I have a more comprehensive log, if you'd like, but only for those years.

Most of the time a company has their own internal logs, and that's what I was trying to find here. I found it for 2009, 2010, but that was it. That's the only thing I could find in the database, so I have that available if you'd like to see it.

Q. My question is on Schedule 12, did you audit Schedule 12 to see if it was a comprehensive list?

A. No, I didn't specifically. I would assume there's no list that could be comprehensive and catch every communication, unless the company specifically did that realtime, and I don't have evidence -- I can't find Bard's copy of it. I'd prefer Bard's copy of it if you have it.

Q. Let's look at Schedule 13. Did you prepare this?

A. No, I did not. This is just a -- the dates of different filters.

Q. Do you know who prepared it?

A. I do not.

Q. With regard to schedule -- looking at Schedule 13 for a minute, have you ever -- well, let me ask you this: Have you ever actually seen a recovery filter, the actual device?

A. I don't think I've seen the actual device.

Q. Have you ever actually seen a G2 filter?

A. I don't think I -- I've seen it represented by Bard in its documents and in their schematics, but they didn't provide any to FDA as far as I know. I have what was provided to FDA.

Q. Have you ever seen any actual filter by any manufacturer?

A. I've reviewed the schematics of those. I have the pictures and schematics that were provided to FDA, and that's what -- we would not normally get the actual device, we'd get the picture and schematics.

Q. So is the answer to my question that you have not seen any actual filters as opposed to schematics?

A. I have no idea whether I've ever seen a filter or a schematic.

Q. But you don't recall?

A. I don't recall whether I saw the schematics.

Q. Did you review any of the IFUs for the Greenfield filter?

A. Yes.

Q. Did you review the IFUs for the Birdsnest filter?

A. I have several of the -- I'd have to double-check. I certainly did Greenfield. I have Cortus, Trapeze. I'd have to double-check on my file whether I have Birdsnest. I certainly have a summary, I believe I reviewed the 510(k) summary for that public document. I'd have to go back and check if the IFU is part of it.

Q. Did you make a comprehensive survey of all competitive filter IFUs?

A. I tried to search -- I tried to search -- and, again, I had access to the Bard database and I did with regard to what was provided in the Bard database, and in addition, I have, I think, a comprehensive list of the 510(k) summary basis for clearance that FDA has made public.

Q. And who went and obtained those summaries from the public FDA records for you?

A. I asked Wendy to help me make sure -- I mean, I may have had some to make sure that I had everything that was on the FDA website that was available.

Q. Did you do any independent review of the MAUDE database on the FDA website for your work in this case?

A. Yes, I've searched the MAUDE database. But

I've realized -- well, I've gone to the MAUDE database and looked at Bard's adverse reports both for malfunction and serious injury. What I've done is I relied more -- I mean, you can't print out the entire database. What I've done is look at the entire database that Bard has on MAUDE, rather than what MAUDE has on MAUDE because it's harder to print it off. You can only print it off by ten or 25, and yet I have thousands in the database.

Q. Schedule 14 is a summary of Bard communications to doctors. Who prepared that for you?

A. Bard, in essence. I mean, all this is is the actual -- these are Bard letters, so these are the actual letters of dear doctor behind you, so these are Bard documents.

Q. Exhibit or Schedule 15 is a list of alternatives to IVC filters; is that correct?

A. Yes.

Q. And who prepared that for you?

A. That was -- I don't know the name of the individual. Again, this was, you know, sort of standard textbook of -- you know, for how to deal with VTEs, it should be just objective textbook data.

Q. But somebody else and not you chose which things to put in this file?

A. Well, you could save -- well, no -- well, the goal was, again, to be as comprehensive. If you have other alternatives that are not in this chart, let's put 'em on this chart. I just want to have a comprehensive database. These are database kinds of schedules so we have the data. There was no intent to limit anything. In fact, the whole goal is if you and I want to talk about this question, we would have it all in front of us to make sure we would have the data. So, again, there is -- there should be no limiting; right? This is meant to be within the confines of what's humanly possible to be comprehensive.

Q. That was not my question. It's very simple: You yourself did not choose which ones would be put on here, someone else that prepared this chose what would be on here; correct?

A. No. Someone chose per my direction to be comprehensive and make sure that we listed the comprehensible alternative therapies, so they were acting under those instructions. Whether they did that or not, we can discuss, but as best I can see, it's pretty comprehensive, it may not be perfect.

Q. Schedule 16 is simply a listing of the two public health notifications from the FDA; correct?

A. Yes.

Q. Schedule 17 appears to be a summary of citations from the SIR guidelines; is that correct?

A. It is a -- it's more specific. For every article mentioned, this is a listing of what filter the article covers, so it's a very specific -- it's a very specific listing.

Q. Who prepared this for you?

A. I don't -- I don't recall specifically. Again, it's just per each footnote, it discusses -- it just lists what filter was in each footnote.

Q. Schedule 18 attempts to identify relationships between SIR guidelines, authors, and IVC filter companies; is that correct?

A. Yes.

Q. And what's the purpose of this?

A. Well, this is just, again, based on a database, on Bard's database, was there anyone on the SIR article or acknowledgments that are listed as the authors and what their relationship, if any, with Bard, so that's just to have that and the citation so we can find them.

Q. Dr. Clemick Grassi, which guidelines was he the author of?

A. So certainly 2003, I'd have to go back and check the updates on that. I have them here.

Q. Do you know whether doctor Grassi had any

relationship with Bard in 2003 when the guidelines were published?

A. I mean, this is, again -- this is the -- what I've been able to ascertain is what's cited in footnote 1.

Q. Cited in what, I'm sorry?

MR. LOPEZ: Footnote 1.

THE WITNESS: I mean, so he -- I have -- and we can go and we can pull it up -- I have a -- in doctor Grassi's deposition what he states about his relationship unrelated to his deposition.

BY MR. NORTH:

Q. So as you sit here today, you don't have a recollection whether he worked with Bard at the time he did those guidelines, do you?

A. I have only the two citations and testimony. I don't have -- I don't believe -- I have to go back and check the transcript -- happy to do that -- and see whether he's testified -- sorry, if he's testified on dates. I don't recall that.

Q. Schedule 19 is a compilation of deaths purportedly related to the filters; correct?

A. Yes.

Q. Who prepared this for you?

A. I don't remember who prepared it, but I was

going through deaths as I was looking at this, and you can see them on the timeline. I don't know who actually put these together, but they were basically to search the database for any deaths that were associated with Recovery and G2 and Eclipse, again in the database, to search the database for specific report of death.

Q. Is it your opinion that each of these instances reflected in Schedule 19 presents a situation where the filter was a causative factor in the death?

A. This is only a list of deaths that Bard related to be associated with the filter. I'm not here as a causation expert.

Q. So just because these incidents are listed does not mean necessarily that the filter was the cause or a cause of the death?

A. You have to talk to other -- I'm not here as a causation expert. This is just, for regulatory purposes, obviously the number of deaths and what was going on was important.

Q. Schedule 20 is a summary of fatigue resistance testing. Do you know who prepared that for you?

A. I believe Richard did, the same Richard, the engineer who prepared the -- you know, so he was able to, you know, go through the testing results and just put the testing results down.

Q. Did you make any revisions to that?
A. No. There wasn't -- I mean, I went through these. There didn't seem to be any need to do that. I reviewed them.
Q. Schedule 21 is a summary or just an itemization of the 483 and FDA warning communications; correct?
A. Yes.
Q. Who prepared this for you?
A. So I believe Laura Smith prepared this, if I'm correct.
Q. She's from the same firm as Ms. Saic; correct?
A. Yes.
Q. Schedule 22, corrosion test results of the modified recovery filter by CC Technologies. This is just a test report; correct?
A. Yes, because it's cited in the report and CDC schedule.
Q. Schedule 24, comparative corrosion results with other competitive filters. Was this prepared by that same engineering paralegal you referenced?
A. I'm not sure. It's possible not. I don't recall. Again, these are just Bard's corrosion testing that had anything to do with other filters too.
Q. Did you make any revisions to Schedule 24?
A. No, but I reviewed it and found it to be

complete.

Q. Oh, I think we skipped 23. 23 are just some photo micrographs; correct?

A. On corrosion, yes, that's from the CC Technologies report.

Q. 25 is a summary of testimony concerning the signature on the recovery filter 510(k); is that correct?

A. Yes.

Q. Who prepared this for you?

A. I don't recall who prepared this. It may have been Shelley Blas who did this.

Q. And remind me again who she is?

A. In Howard Nations firm.

Q. Did you read the deposition of Kate Fuller?

A. Yes.

Q. Did you read the deposition of Carol Vierling?

A. Kay Fuller and Mary Edwards. I'm not sure I read all; I certainly went through it. Hold on a second. Let me just check my records and see what I can recall to answer your question.

So -- let me be accurate. I have to go back, I've got to go back and double-check that. I'm not pulling it up because I have a lot of depositions only by their Bates numbers so I can't tell. I'd have to go

back and review that. I can do that at lunch, if you want.

Q. As you sit here today, do you recall who signed the -- let me ask you this: 510(k) applications have a certification of accuracy of some sort; correct?

A. Several different parts of a 510(k). There's multiple signature lines at different points in the 510(k).

Q. Do you know who signed those various certifications in the 510(k) for recovery filter?

A. The actual -- show me the page that you're referring to specifically because there's multiple signature lines; right? And there's also, as I remember -- and I have to go back and review -- there was a library copy and there's a copy submitted to FDA, and I will simply put -- I'd have to review exactly which page you're talking about, so let's pull the document.

Q. So as you're sitting here right now, you cannot tell me, without looking at the document, who actually signed the certification on the 510(k)?

A. I'd want to check and pull the document and, again, which copy you're talking about, because I think there were two copies, if my memory serves me right, there was a library copy and there was a copy submitted

to FDA, so we'd have to pull both copies.

Q. Number 26 is Dr. Betensky's expert report that you reference; correct?

A. Yes.

Q. And this is dated August 28th of 2016?

A. Yes.

Q. And since you haven't read her deposition, you're not able to tell us whether this report is consistent or inconsistent with her deposition, are you?

A. I have to go back and double-check whether I read her -- I think my answer was I have to go back and check whether I read her deposition.

Q. Number 27, Schedule 27 is simply the spreadsheet from Dr. Betensky; correct?

A. Exactly.

Q. What is Schedule 28?

A. So this is a listing which meant to be of documents -- of times when Bard used comparative adverse event data, so in Bard's document, whether they compared adverse reporting rates of their filters versus another filter. So I was looking for their use of that methodology.

Q. Who prepared Schedule 28 for you?

A. I think it was someone at Mr. Lopez's shop. I don't know who did it. But it's basically -- they

should be primarily from my report.

Q. Did you make any revisions to Schedule 28?

A. I looked at it, saw that it was complete, and I didn't think there was any need to be -- again, it tries to put in one place that aspect, those things in my report.

Q. Schedule 29, who prepared this?

A. Shelley Blas. This is just a listing of the preclinical testing that was cited in the 510-Ks. Again, an administrative compilation of all the preclinical testing that's cited in the 510(k) so if we wanted to be able to find a study, a preclinical study, we have that list.

Q. And did you make any changes to that?

A. Yes. There was one, the last page. It wasn't clear whether that was in the testing applied to Recovery or G2, so I asked them to make that clearer.

Q. Do you know any of the Bard present or former employees whose names you saw referenced in the various documents?

A. Have I met them personally, are you asking me?

Q. Yes.

A. You know, you read so many documents you feel like you know them. So I don't think I know them. I'm not saying I've never met them; I mean as FDA

Q. Were the test reports that you are relying on saying that Bard did not meet its own specifications for migration resistance and/or caudal migration, were those premarket or post-market tests?

A. The migration resistance, the change in the acceptance criteria, I believe, was premarket of the G2, again modified G2, there are multiple ones. The caudal migration test, I believe, was November 27th, 2006, so I believe that was post is my memory, but the initial migration tests, Bard failed compared to SNF and then changed the standard was premarket.

Q. You have told us why you believe the G2 was adulterated. Do you believe the G2 was misbranded?

A. Yes.

Q. In what way?

A. Well, because the IFU -- if you turn in my report, if you look at the IFU, the IFU simply talks about migration as, for example, being as with all filters. There's nothing in the IFU for G2 that points out that it failed on caudal migration, there's nothing in there that shows there's increased risk of migration compared to SNF. So it's certainly misleading because it makes -- the IFU makes it sound like this is all filters, when clearly there's evidence of increased risk.

but I certainly probably have looked at IFUs when they come to companies that I've been involved in, but I normally don't draft them, but I certainly was responsible for deciding whether IFUs were misleading or not.

Q. But you personally, as I understand it, have not drafted an IFU, whether at the FDA or elsewhere?

A. No. But I reviewed them and regulated them and decided whether they were in compliance with the Act.

Q. Is it your opinion that Bard should have recalled the G2 filter at any time?

A. Should have never been on the market.

Q. Well, assuming that it was on the market, as it was introduced to the market, should it have been recalled at some point?

A. It should have never been on the market because it didn't have a legally based predicate because RNF shouldn't have been on the market, and certainly when it became adulterated on November 2006, it should have been -- when you fail the caudal migration, which was the -- again, the rationale for substantial equivalence, these things didn't migrate. Once you find that it didn't meet its performance test, I mean, you either either fix it or take it off the market. That's the basis of adulteration.

Q. There were incidents of caudal migration in the Everest study; correct?

A. Sure, that's correct.

Q. And the Everest study was provided to the FDA, wasn't it?

A. That's correct.

Q. And the data and report of the caudal migrations in the Everest study were disclosed to the FDA?

A. That's correct. But the failure to meet the performance spec in the representation that Bard made to FDA was not disclosed to FDA. So G2 was worse than RNF, it was worse than SNF, it failed on the performance spec. That was never -- the basis of substantial equivalence was basically undercut by that test. That was never disclosed to FDA.

Q. Do you know whether physicians generally that work with filters consider caudal migration to be a significant problem?

A. So I believe that -- hold on a second. Let me just -- give me one second to answer that. So let's go to Dr. Ciavarella's own words, he's certainly a physician, he certainly works with filters, and he certainly is, I would assume, knowledgeable.

So if you look at his February 9, 2006, he